IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC., and BAYER HEALTHCARE LLC,	
Plaintiffs,	
v.	**C.A. No. 05-349-GMS**
BAXTER INTERNATIONAL INC., and BAXTER HEALTHCARE CORPORATION,	**Jury Trial Demanded**
Defendants.	**REDACTED VERSION DI 178**
BAXTER HEALTHCARE CORPORATION,	
Counterclaimant,	
v.	
TALECRIS BIOTHERAPEUTICS, INC., and BAYER HEALTHCARE LLC,	
Counterdefendants.	

PLAINTIFFS' ANSWERING CLAIM CONSTRUCTION BRIEF

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I. NATURE AND STAGE OF PROCEEDINGS

Opening briefs on claim construction were filed with the Court on October 27, 2006. A hearing on claim construction is scheduled for December 14, 2006. This is Plaintiffs' answering brief[1].

II. SUMMARY OF THE ARGUMENT

We refer the Court to the Introduction Section of the argument below.

III. STATEMENT OF FACTS

Claim 1 of the '191 patent, the broadest claim at issue, claims a process for making intravenously administrable immune serum globulin ("ISG"), also referred to as intravenous immune globulin or IGIV. This process comprises two steps: first, treating the solution with a solvent and detergent under conditions sufficient to substantially reduce viral activity and to increase anticomplement activity; and second, incubating the solution under controlled conditions of time, temperature, pH, and ionic strength such that anticomplement activity is reduced to an acceptable level suitable for intravenous administration to a patient. JA150, col. 11, ll. 34-44. Plaintiffs refer the Court to our opening brief for a more thorough discussion of the pertinent technical background.

Defendants expend pages to provide additional information not pertinent to the claim construction questions. Many of the Defendants' "facts" are inaccurate. Rather than consume space rebutting and correcting irrelevancy, we turn to the task at hand. Our silence should not, however, be viewed as assent to Defendants' inaccuracies.

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[1] As with Talecris' opening brief (hereafter referred to as "TOB"), we continue to refer to the Joint Appendix as "JA". We refer to Baxter's opening brief as "BOB".

IV. ARGUMENT

A. Introduction

The primary claim at issue, claim 1, is uncomplicated and straightforward. Therefore, virtually all of the disputed claim terms should be given their ordinary meaning. The context of the claim as a whole and the specification are fully consistent with these plain meaning interpretations. Plaintiffs' constructions fully comport with *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

Defendants ignore the controlling Federal Circuit law in *Phillips*. Their proposed constructions improperly import limitations, preferences, examples, and extraneous terms from the specification into the claims in order to rewrite them. *Id.* at 1323; *see also SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1286 (Fed. Cir. 2005). Defendants point to no manifest exclusion or disavowal warranting such gross limitations. *See Phillips*, 415 F.3d. at 1317. Defendants' constructions are also improper because they rest largely on extrinsic evidence, which Defendants mischaracterize. *See id.* at 1324.

Two central themes permeate Defendants' arguments. First, Defendants urge the Court to hold claim 1 invalid for indefiniteness. This approach is procedurally defective. In *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, this Court explicitly ruled that efforts to invalidate claims for indefiniteness in claim construction briefs "will not be sanctioned". No. 02-148, 2003 WL 124149, at *1 n. 1 (D. Del. Jan. 13, 2003) (Sleet, J.). Judge Jordan similarly has ruled that invalidity arguments are not appropriate in a claim construction brief. *Ampex Corp. v. Eastman Kodak Co.*, No. 04-1373, 2006 WL 3042144, at *1 n. 1 (D. Del. Oct. 26, 2006) ("The validity of a claim is not an issue of claim construction, but should have been addressed in a motion for summary judgment. I will not convert Defendants' claim construction argument into a motion for summary judgment."); *accord*: *Phillips*, 415 F.3d at 1328. Defendants' reliance on *Honeywell* is

misplaced because in *Honeywell* the accused infringer moved for summary judgment. *Honeywell Int'l, Inc., v. Int'l Trade Comm'n*, 341 F.3d 1332, 1337 (Fed. Cir. 2003).

Secondly, Defendants' arguments rest on several false premises, upon which they then reach a faulty conclusion, which is in violation of *Phillips*, namely, that Claim 1 is limited to the single embodiment of a particular solvent/detergent combination (TNBP/cholate) at a specific pH (pH 7.0). *See Phillips*, 415 F.3d at 1323.

Defendants' first false premise is that anticomplement levels must always rise to levels that are "unacceptable". This is incorrect. Claim 1 contains no such limitation, and the '191 specification itself teaches that the ACA increase may be to levels less than those characterized as "preferred" for intravenous administration. *See* TOB 17. Thus, one of Defendants' central arguments depends on improperly reading a limitation into the claim that is refuted directly by the specification. *See Phillips*, 415 F.3d at 1323.

Defendants' second false premise rests exclusively on extrinsic evidence. They argue that other solvent/detergent systems, such as TNBP/Tween, are inoperable based on experiments not reported in the '191 patent, which supposedly show that ACA does not always elevate to the assumed "unacceptable" level. Thus, this premise, again in violation of Federal Circuit law, improperly rests not on what is disclosed in the specification but on what is not disclosed in the specification. *See id.* at 1324.

Defendants do not stop here; their arguments also are inconsistent.

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This contention requires that the word "comprising" appearing in claim 1, which the Federal Circuit has held permits inclusion of additional process steps, be read out of the claim altogether. *See CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1235 (Fed. Cir. 2005) ("The

transitional term 'comprising' ... is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.") (internal quotations and citations omitted).

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Claim 1 neither includes, nor requires that, only one particular assay be used to measure anticomplement activity levels.

Finally, Defendants contend that the phrase "acceptable" is incapable of definition. This argument is contradicted by Judge Jordan's decision in *Pharmacia & Upjohn Co. v. Sicor Inc.*, 447 F.Supp.2d 363, 370 (D. Del. 2006). Defendants' "alternative" argument that "acceptable" equates to precise numerical preferences set forth in the specification, which they say equates to a single company's FDA limits governing manufacture and release of these types of products, also violates Federal Circuit law by reading preferences into the claim. *SanDisk*, 415 F.3d at 1286 ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations.") (internal quotations and citations omitted).

In effect, Defendants are asking this Court to re-write and narrow claim 1 based on extrinsic evidence that is not consistent with the language of the claim or intrinsic evidence, in violation of the well established rules of claim construction set out in *Markman* and *Phillips*. This is not the claim intended either by the Patent Office or the applicant, and should be rejected by the Court[2].

When all of Defendants' legally bankrupt constructions are combined, claim 1 would be re-written to read as follows:

> A method of treating a solution of antibodies that may have virus activity, the method [comprising] consisting of
>
> > a) contacting the solution with a trialkylphosphate and [a detergent] sodium cholate at pH 7.0 under conditions sufficient to substantially

[2] We attach as Exhibit "A" a proposed form of order setting forth succinctly Plaintiffs' construction.

reduce [any virus] activity of all viruses in solution and always resulting in an increased level of anticomplement activity, "the amount of protein capable of activating 50% of the complement in an optimally titered complement and red blood cell/hemolysin system, as determined by the particular anticomplement activity assay used to obtain the anticomplement activity data reported in the '191 patent" to an unacceptable level as measured by CH_{50} units; and

b) then incubating the solution of step a) before any other processing steps occur and immediately after step a) under conditions of controlled time, pH, temperature and ionic strength, such that the increased anticomplement activity of the solution from a level acceptable for intravenous administration to a level unacceptable for intravenous administration as measured by CH_{50} units is reduced to an acceptable level suitable for intraveneous administration, which is less than about 45 CH_{50} units/mL for a 5% solution and less than about 60 CH_{50} units/mL for a 10% solution.

B. Plaintiffs' Proposed Construction Of The Claim Terms Should Be Adopted Because It Most Closely Aligns With The Language Of The Claim As A Whole And With The Specification

1. The Term "Any Virus Activity" Cannot Mean "All Virus Activity"

Claim 1 recites, in relevant part, "under conditions sufficient to substantially reduce **any virus activity**."[3] As explained in our opening brief (TOB 10–12), the clear meaning of "any virus activity" within the context of claim 1 is "**any virus activity which is substantially reduced by the conditions of step a)**." This plain and ordinary meaning requires no construction.

Defendants ask the Court to replace the word in the claim "any" with the word "all", thus changing the intended scope of the claim.

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[3] As with our opening brief, Plaintiffs' proposed constructions are in bold at the beginning of each section.

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Defendants thus distort the clear scope of solvent/detergent viral inactivation provided in the claim and in the specification of the '191 patent (*see*, *e.g.*, JA145, col. 1, ll. 49–54). They ignore the Neurath patent, U.S. Patent No. 4,540,573, which was incorporated by reference into the '191 specification. JA48; *see* JA145, col. 1, ll. 46-47. Neurath plainly indicates that while the solvent/detergent step may indeed inactivate more than lipid-enveloped viruses, it does not inactivate "all" viruses. Neurath describes solvent/detergent treatment as relating to "the inactivation of viruses, especially lipid coated viruses" (emphasis added). JA51, col. 1, ll. 9–10. Inactivation of "all" viruses is not mentioned in the specification of either the '191 patent or Neurath.

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2. The Term "Under Conditions Sufficient To Substantially Reduce Any Virus Activity And Resulting In An Increased Level Of Anticomplement Activity" Should Be Accorded Its Ordinary Meaning

Defendants attempt to re-write the claim by deleting the claim language, "sufficient to substantially reduce any virus activity" from the claim. This is improper. As written in claim 1, the full term is **"under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of ACA"** (emphasis added). *See BBA Nonwovens Simpsonville, Inc. v. Superior Nonwovens, LLC*, 303 F.3d 1332, 1344 (Fed. Cir. 2002) (rejecting infringer's construction for ignoring the word "positioned" and reading a limitation out of a claim). All elements of the claim term are necessary. The presence of conditions under which substantial

virus reduction may occur and which result in an increase in the level of ACA is the very point of step a) of claim 1.

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First, it is procedurally improper. *See Pharmastem Therapeutics*, 2003 WL 124149, at *1 n. 1. Secondly, it is substantively incorrect. It is evident on the face of claim 1 that the solvent/detergent step which Defendants seek to eliminate from the claim term, as fully exemplified in the specification by numerous examples and data, results in an increase in ACA. Defendants do not argue that one skilled in the art could not determine whether a particular solvent/detergent step results in an increase in ACA because, as shown in the specification and known in the art, this can be readily determined. *See, e.g.*, JA145, col. 1, ll. 25–31 and references cited therein.

Defendants argue on the basis of extrinsic evidence that claim 1 can embrace only a particular solvent/detergent combination (TNBP/cholate) and only at a particular pH (pH 7.0). Defendants thus seek to import a single embodiment into claim 1 in violation of *SanDisk*. *See* 415 F.3d at 1286.

Defendants begin by mischaracterizing the specification, arguing that it overstates the applicable solvent/detergent conditions that may elevate ACA.

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Rather, the patent teaches how to perform the solvent/detergent step and provides examples of solvent/detergent viral inactivation that increase ACA. It fully exemplifies this increase with data from two solvent/detergent combinations under differing conditions. There is no requirement that all solvent/detergent processes must always increase ACA under all

conditions, and no requirement that all solvent/detergent combinations must be exemplified. *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 392 F.Supp.2d 676, 681 (D. Del. 2005) ("'It is not necessary that a patent applicant test all the embodiments of his invention; what is necessary is that he provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims.'") (*quoting Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991)); *accord*, *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) ("It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art."). Defendants' position also ignores the fundamental point that if a solvent/detergent step does not increase ACA, then the solvent/detergent step is not within the scope of step a).

Building on their misreading of the specification, Defendants then mischaracterize extrinsic evidence to support their erroneous "unacceptability" claim limitation and their importation of a single embodiment (TNBP/cholate at pH 7.0).

The '191 patent specifically exemplifies a TNBP/Tween-treated sample having an ACA value of 68 CH_{50} units/mL, an increased level of ACA that is reported in Table 1 of the patent. This sample fully supports all limitations of claim 1. *See* JA147, col. 6, ll. 45–63.

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This argument is irrelevant to the

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claim construction issues. The Federal Circuit has repeatedly cautioned that extrinsic evidence should not be used to contradict unambiguous intrinsic evidence. *Phillips*, 415 F.3d. at 1324.

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This argument contradicts the intrinsic evidence, which clearly exemplifies pH 5.8. JA148, col. 8, ll. 38–52; *see* also JA149, col. 9, ll. 23–36 (Table 7). The argument hinges on the fallacy that the increase in ACA must be to an "unacceptable" level, and that to meet this unacceptability limitation, ACA levels must be higher than ACA levels of the preferred embodiments. *See* JA147, col. 5, ll. 57–64.

As we explained in our opening brief (TOB 13–15), Defendants' construction not only reads preferred embodiments into the claim, it also ignores dependent claims which cover the very embodiments by which Defendants seek to limit claim 1, and thus contravenes the doctrine of claim differentiation (*see* TOB 14–15).

Defendants' construction even reads preferred embodiments out of the claim. After concluding that solvent/detergent treatment must increase ACA to an unacceptable level, which is a conclusion devoid of evidentiary support, they arbitrarily assert that these threshold ACA levels should be set by a "preferred" embodiment rather than a "more preferred" embodiment. *See* TOB 15. Defendants thus apply arbitrary "unacceptable" ACA levels to conclude that the majority of samples treated with solvent/detergent at pH 5.8 had "acceptable" ACA levels and, therefore, that the pH 5.8 condition should be excluded from the scope of the claim.

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Phillips specifically provides that claims should not be limited to the preferred embodiments. 415 F.3d at 1323.

In order to reach Defendants' construction of this term, one must re-write the claim term by improperly limiting the term to one of the preferred embodiments, excluding other preferred embodiments, and then supporting this construction with extrinsic evidence.

3. The Term "Increased Level Of Anticomplement Activity", Which Does Not Contain A Limitation To "Unacceptable", Should Be Given Its Ordinary Meaning

Defendants ultimately are forced to admit that "[u]pon first glance, it might appear that the ACA level must merely increase to some undetermined amount."

This is precisely Plaintiffs' position.

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Not only does this construction belie the plain meaning of the term but, as explained in our opening brief (TOB 16–18) and above, it does so by importing into the claim the limitation "unacceptable" that is unsupported in the intrinsic record.

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This logic is faulty. It depends on adding the word "unacceptable" to claim 1 and then fabricating its definition. In doing so, Defendants improperly import preferred embodiments from the specification into the claim as their definition

of "unacceptable." There is no requirement in any claim that the ACA of every manufactured lot increase following step a) to a level that is above a specific numerical level.

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The only claim limitation related to acceptability is that the ACA of the final post-incubation product following step b) "is reduced to an acceptable level suitable for intravenous administration." JA150, col. 11, ll. 43–44.

There is also no requirement in claim 1 that the ACA levels increase above FDA release limits. There are no claimed numerical limitations; only a qualitative increase in ACA levels is required.[5]

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The arguments did not depend on a particular claim interpretation that the ACA increase must always be to an "unacceptable" level, and no such limitation was required by the Board. Indeed, to the contrary, the Patent Office assumes the broadest possible interpretation of claims during prosecution. *See In re Bond*, 910 F.2d 831, 833 (Fed. Cir. 1990). Consequently, because there was no manifest exclusion or clear disavowal by the applicant, i.e., the prosecution history does not require an "unacceptable" limitation, statements by the Patent Office will not act to limit the claim. *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1345 (Fed. Cir. 2005).

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[5] **REDACTED**

These numerical values define the upper levels that Defendants contend are acceptable. While some Gamimune-N S/D lots exhibit increased ACA to above these release limits following solvent/detergent treatment, others do not. But in no case is there support for Defendants' contention that unacceptability and Talecris' particular release limits equate. *See, e.g.*, data presented in JA147–149, Tables 1, 3 (Initial Testing data), 5 (sterile bulk), 6 (day 0), and 7 (Sterile bulk). *See* TOB 17. Moreover, as Defendants acknowledge, in the United States, release criteria required by the FDA will depend on the particular product and process. *See* BOB 8–9, n. 3–4. It would be highly inappropriate to limit the claim to these levels.

Defendants' statement that the intrinsic record indicates that step a) results "in an increase in ACA from the starting material" (BOB 28; emphasis in original) also hardly supports the insertion of "unacceptable" in step a). The intrinsic record explicitly described the "control" which Defendants seek to equate to the "starting material" as illustrative and stated that it was only "used in that example". JA98.

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As the specification teaches, any increase in ACA following step a) is undesirable, even if the level does not exceed regulatory requirements for intravenous administration. JA149, col. 9, ll. 38–41. As the specification teaches, ACA should be as low as possible. JA147, col. 5, ll. 54–55. Accordingly, the term "increased level of anticomplement activity" should be given its simple, plain meaning: an **anticomplement activity level which increases as a result of contacting the solution with a solvent and detergent**. Defendants' proposed construction should be rejected.

4. The Term "Anticomplement Activity" Means The Ability Of Antibodies To Bind Complement

The term "anticomplement activity" ("ACA") is explicitly defined in the specification of the '191 patent as "**the ability of antibodies to bind complement.**" *See* JA145, col. 1, ll. 9–22 ("The ability of gamma globulin to bind complement"). The words used to define ACA are commonly used and understood in the relevant art.

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And as shown in our opening brief, such a definition is unsupported. *See* TOB at 20–21.

Simply stated, claim 1 specifies neither units of measure nor measurement techniques. Defendants' definition lacks support in the specification. It is contrary to both the plain meaning and the express definition in the specification, and it improperly excludes all but one measuring technique, when, as Defendants admit, there is more than one.

5. The Term "Then Incubating The Solution Of Step a)" Is Clear On Its Face And Permits Additional Processing Steps

The term "then incubating the solution of step a)" should be defined as "**incubating a solution originating from step a) under conditions of controlled time, pH, temperature, and ionic strength, wherein additional steps may be performed prior to said incubating.**" Such a construction is clear from the ordinary meaning of the claim language and the specification. *See Phillips,* 415 F.3d at 1313.

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This argument wholly ignores in claim 1 the word "comprising", a term which clearly denotes that additional processing steps may be present. *See* TOB 21-22; *see also CollegeNet,* 418 F.3d at 1235. Defendants' construction ignores repeated teachings in the specification that intervening process steps may be present. TOB 21-22. It conflicts with the language both of the claim and of the specification, which teaches that additional steps may occur between step a) and step b), steps such as sterile filtration and adjustment of the solution to render it physiologically compatible. *See* JA147, col. 5, ll. 25-41; JA145, col. 2, ll. 10–23. **REDACTED**

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It also defies common sense. Dr. Alonso would not invent a new process that can make a solution of antibodies intravenously administrable, yet exclude other well-known process steps commonly employed by those in the industry. *See Pharmacia*, 447 F.Supp.2d at 369 ("[W]hen you are talking about something that is intravenously injectable, sterility, pyrogenicity, those things are important.") (internal quotations and citation omitted)[6]. Since steps that make the solution suitable for intravenous administration occur between step a) and step b), were the term construed as Defendants have suggested and the intervening steps excluded, the invention would be non-sensical.

Defendants' resort to extrinsic evidence in the form of foreign prosecutions is equally meritless. Prosecution of the European equivalent is not relevant to the construction of claim terms in this case. *See Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006), *aff'g*, 405 F.Supp.2d 495, 505–6 (D. Del. 2005) (affirming Judge Farnan's ruling that "statements made during prosecution of foreign counterparts … are irrelevant to claim construction because they were made in response to patentability requirements unique to … European law."); *see also* BOB 30, n. 9. The amendment to claim 1 of the European equivalent of the '191 patent did not, as Defendants state, occur without prompting from the European Patent Office ("EPO"). BOB 30–31. The European prosecution history clearly shows that the claim amendment was in response to objections by the EPO for lack of clarity under Article 84 of the European Patent Convention ("EPC"). *See* Exhibit "D".

[6] Indeed, as Judge Jordan recently held, the person of ordinary skill in the art would know that suitability for intravenous administration requires, *inter alia*, a sterile, pyrogen-free solution. *See Pharmacia*, 44 F.Supp.2d at 370 (Jordan, J.) (Defendant admitted "that for an injectable solution to be suitable for administration to humans and animals, it must be sterile and pyrogen-free. Therefore, I will construe the term 'physiologically acceptable' to mean 'the substance is sterile, pyrogen-free, and otherwise suitable for administration to humans or animals.'"). Compare '191 patent, JA147, col. 5, ll.27–28 (other steps required to render the solution "physiologically acceptable upon injection").

6. The Term "Increased Anticomplement Activity Of the Solution" Is Clear And Unambiguous

The term "increased anticomplement activity of the solution" should be given its ordinary meaning. It is clear as written and needs no construction. As discussed above, anticomplement activity or ACA is defined in the specification. "Increased anticomplement activity of the solution" therefore simply means **an increase in the ACA levels of a solution as a result of contacting the solution with a solvent and detergent**.

As we explained in our opening brief (TOB 23–24), Defendants bifurcate the term into "increased anticomplement activity" and "of the solution," eliminating both context and ordinary meaning. *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir.) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.").

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As noted previously, "increased" does not equate to "unacceptable."

Defendants argue that "of the solution" is indefinite. *Id.* This is improper. *See Pharmastem*, 2003 WL 124149, at *1 n. 1. However, the term "of the solution," even out of context, unambiguously means "the solution from step a) that is to be incubated." There is no lack of clarity despite Defendants' efforts to obfuscate. Plaintiffs thus urge the Court to construe the term in its entirety, consistent with the plain meaning of the term and of the claim in light of the specification.

7. The Term "Acceptable Level Suitable For Intravenous Administration" Is Clear And Unambiguous

The term "**acceptable level suitable for intravenous administration**" should also be given its ordinary meaning. It needs no construction. It is clear on its face. Persons of ordinary

skill in the art would know that when injecting immune globulin intravenously into a patient, ACA must be at an acceptable level, just as they would know that the solution must also be "physiologically acceptable". Defendants are disingenuous when they suggest that they do not know, and that a personal of ordinary skill would not recognize, an acceptable level of ACA suitable for intravenous administration.

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Defendants' indefiniteness argument cannot be squared with reality. We note that in *Pharmacia*, Judge Jordan had no problem construing the phrase "physiologically acceptable" as, *inter alia*, suitable for administration to humans. *Pharmacia*, 447 F.Supp.2d at 370. The patent in this case relates to ACA and requires that ACA be at an acceptable level suitable for intravenous administration.

Defendants' construction relies on an out-of-context quotation from the prosecution history stating, "The acceptable level of ACA generally depends on IGIV concentration and examples (for 5 and 10% IGIV solutions) are described in the second full paragraph of page 9." JA77. The cited passage in the patent indicates that acceptable ACA levels would be less than the disclosed preferred numerical ACA values which correspond to release limits as discussed above. *See* JA147, col. 5, ll. 57–64. Defendants fail to point out that the passage from the prosecution history upon which they rely describes the recited ACA values as examples, and the patent describes the recited ACA values as preferred embodiments. It is improper to draw limitations into the claims from preferred embodiments. *SanDisk Corp.*, 415 F.3d at 1286 ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations.") (internal quotations and citations omitted). Moreover, the specification indicates, as we have shown above, that acceptability does not universally equate to particular

numerical ACA limits. It states, "While there is no strict rule for determining when the ACA level is low enough to be an acceptable level suitable for intravenous administration, IGIV preparations should have ACA levels as low as possible." JA147, col. 5, ll. 51–55.

The term "acceptable level suitable for intravenous administration" should therefore be given its ordinary meaning.

8. The Term From Claim 2, "About 60 CH_{50} Units/mL", Was Not Listed In The Joint Claim Construction Chart, And Claim 2 Is Not Being Asserted;Therefore, No Construction Is Needed

The term "about 60 CH_{50} units/mL" appears in claims 2 and 5 of the '191 patent. Plaintiffs were unaware that the term as it appears in claim 2 required construction since claim 2 was not raised in the Joint Claims Construction Chart.

REDACTED Moreover, Plaintiffs have notified Defendants that they do not intend to assert claims 2, 5 and 6. Therefore a construction of "about 60 CH_{50} units/mL" is neither necessary nor appropriate. *See* TOB 27, n. 4.

In any event, Defendants' arguments relating to "about 60 CH_{50} units" appearing in claim 2 are wrong. Claim 1 does not require either the use of a particular assay or unit of measure. Rather, claim 1 requires that one determine an increase or decrease in ACA.

C. Defendants' Characterization Of "Level Of Ordinary Skill In The Art" Is Unsupportable And Wrong; The Court Need Not Resolve The Disputed Issue Of Who Is The Person Of Ordinary Skill In The Art At This Time

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First, they offer support neither for their description of the skilled artisan nor of the art in which the person is skilled. Secondly, there is no extrinsic evidence before this Court (even the need to establish the person of ordinary skill in the art presupposes the need to interpret extrinsic evidence), nor is there an affidavit of any expert. *See ISCO Int'l., Inc. v. Conductus, Inc.*, No. 01-487, 2003 WL 279561, at *6 n. 8 (D. Del. Feb. 10, 2003) (Sleet, J.)

(denying motion for summary judgment because testimony was needed regarding the level of skill in the highly technical art at issue).

The Court should therefore refrain from ruling on this point until an appropriate evidentiary record has been presented. While Plaintiffs dispute Defendants' characterization of the level of skill in the art as unduly understated, the Court need not resolve this question now because Plaintiffs' proposed claim construction is proper even under Defendants' inappropriate view.

V. CONCLUSION

For the foregoing reasons, we respectfully submit that the interpretation of the claims urged by Plaintiffs should be adopted by the Court. Plaintiffs' proposed constructions most closely comport with the language of the claims, the specification, and applicable law.

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CERTIFICATE OF SERVICE

I hereby certify on this 27th day of November, 2006 I electronically filed the foregoing Plaintiffs' Opening Claim Construction Brief with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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I also hereby certify that a true copy of the foregoing document was served upon the following in the manner indicated on November 27, 2006.

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